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Honorable William H. Pauley III United States District Court Judge The Daniel Patrick Moynihan United States Courthouse 500 Pearl Street, Chambers 2210 Court Room 11D New York, NY 10007

Re: McNeil-PPC, Inc. et al. v. Perrigo Company, et al. Civil Action No. 05-CV-1321

DEC 26 2006

## Dear Judge Pauley:

In preparing for trial of this matter during November, I became aware that through inadvertence, Perrigo had failed to produce a portion of its ANDA to McNeil. Similarly, I discovered that McNeil had failed to produce portions of its NDA to Perrigo. I informed Mr. Nimrod of the general content of the material Perrigo had overlooked producing, and indicated I would look more closely at what McNeil had not given us, to determine whether we needed to do anything to correct these failures.

Upon closer inspection, I determined that the portions of the McNeil NDA not produced contained lists of publications which had been provided to the FDA, many of which are prior art to the '340 patent in suit, and others of which may refer to such prior art. Thus, on November 27, 2006, my associate Andrea Zydron emailed a request that those publications be produced. A copy of that email is forwarded herewith.

On December 1, 2006, Mr. Kris Keil for McNeil responded that:

In our November 14, 2005 response to Perrigo's document request regarding the Pepcid Complete NDA, Plaintiffs were very clear as to what documents they would produce: "a history of submissions to the FDA for the requested NDAs; FDA communication logs; tables of contents and supplements thereto, including patent information from the Orange Book; and submittal and approval letters for the requested NDAs." Perrigo interposed no objection to what we specified as being within the proper

The full copy of his email is also forwarded herewith.

I had our people investigate further, and found that Ms. Zydron and Mr. Underwood had requested, off the record, that McNeil produce the McNeil NDA at the deposition of Ms. Freeman on January 30, 2006. Mr. Daignault for McNeil responded that he believed the NDA had already been produced. On January 31, 2006, Mr. Underwood confirmed this request in writing (copy forwarded herewith). There is no subsequent written correspondence on this point, and our team proceeded under the assumption that we had the McNeil NDA.

On December 13, 2006, I reported the foregoing to Mr. Nimrod. (Copy forwarded herewith.)

Mr. Daignault's response of December 18, 2006, also forwarded herewith, refers to another oral exchange concerning the NDA which he alleges took place at some time between him and Mr. Underwood. Mr. Underwood recalls agreeing that we did not need copies of the clinical studies themselves. However, Mr. Underwood never had any understanding that portions of the NDA disclosing prior art were not being produced.

It is respectfully submitted that the burden on McNeil to produce the requested publications is minimal, in comparison to the potential significance of the documents. While Perrigo believes the '340 patent is invalid with or without additional prior art, the documents McNeil was aware of and now seeks to avoid producing may reveal further attempts by McNeil to conceal pertinent prior art. Nor does Perrigo have any way of knowing, without seeing the art, whether some of it may be more pertinent than art already of record in the case.

While Perrigo is attempting to obtain copies from public sources, and has obtained some copies, 1 it is not always possible. For example, item 55 is merely indicated as "published clinical literature." Another reference is called "Labeling for Pepcid AC Acid Controller." Some are "protocols" which do not seem to be available, though they appear to have publication dates. Accordingly, Perrigo requests that McNeil be ordered to provide the requested publications, or at least be given permission to file a motion for same.

Respectfully submitted,

ames A. Mitchell

ames Q. Mather Application denied. Discovery closed long ago. These materials

We have been able to obtain copies of items 14, 16 and 17 of volume 1.8, 43-47, 49 and 50 of volume.

1.16, and item 16 of volume 23.

SO ORDERED:

January 8, 2007

Cc: Harold W. Reick
Steven I. Underwood
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Aaron J. Wong
John G. Gilfillan III
Alexis Gander
Raymond N. Nimrod
Ronald M. Daignault
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